

PUBLIC INFORMATION & COMMUNICATION SERVICES (PICS)
NIH - TASK ORDER

RFTOP#131 TITLE: Support Services for Human Studies Division of the EPA.

PART I – REQUEST FOR TASK ORDER (TO) PROPOSALS

A. Point of Contact Name: Fran Legg, Contract Specialist (919) 541-3567.

Proposal Address:
[US Mail]

U.S. Environmental Protection Agency
Attention: Fran Legg
RTP Procurement Operations Div. (D143-01)
Research Triangle Park, NC 27711

Proposal Address:
[Hand Delivered]

U.S. Environmental Protection Agency
Attention: Fran Legg
RTP Procurement Operations Div. (D143-01)
4930 Old Page Road
Research Triangle Park, NC 27709.

Billing Address:

U.S. Environmental Protection Agency
RTP Financial Management Center (D143-02)
Attention: Contract Payment
Research Triangle Park, NC 27711

B. PROPOSED PERIOD OF PERFORMANCE:

Base Period: October 22, 2003 - October 21, 2004
Option 1: October 22, 2004 - October 21, 2005
Option 2: October 22, 2005 - October 21, 2006
Option 3: October 22, 2006 - October 21, 2007
Option 4: October 22, 2007 - October 21, 2008

C. PRICING METHOD: Fixed Price with a Cost Reimbursable Line Item. Please use pricing sheet in Clause B.1 to submit prices. Cost Reimbursable ceilings have been established by the EPA.

D. PROPOSAL INSTRUCTIONS: To expedite EPA evaluation and ensure evaluators identify pertinent information, technical proposals should be organized to follow and address each of the evaluation criteria.

Submit an original and 4 copies of the technical proposal and an original and 4 copies of the proposed pricing sheets (complete B.1 of Attachment 4).

Proposals shall be on letter size (8.5" by 11") paper with page margins of at least 1.0 inch. Technical proposals are limited to 30 pages using a font size no smaller than 10 point. Personnel resumes shall be included in the technical proposal as an appendix. The appendix of resumes will not be counted toward the technical proposal page limit.

E. RESPONSE DUE DATE: June 05, 2003 at 1200 noon Eastern Standard Time.

F. TASK DESCRIPTION/STATEMENT OF WORK:

The Contractor shall provide services to support the research programs of the Human Studies Division (HSD), National Health and Environmental Effects Research Laboratory (NHEERL), U.S. Environmental Protection Agency (EPA). Services provided by the Contractor shall include the recruitment, screening, arrange testing, scheduling, payment, and other incidental support activities for paid volunteer subjects participating in human experimental studies. Occasional followup with volunteers who previously participated in HSD studies is also included. Although most studies involve all of these services, occasionally studies may require only limited Contractor support. The HSD research programs supported by this task order involve studies conducted in the EPA's Human Studies Facility (HSF) located on the campus of the University of North Carolina at Chapel Hill (UNC-CH), Chapel Hill, North Carolina, as well as off-site studies. Research is conducted by staff from the EPA, UNC-CH, guest and visiting researchers, and other organizations granted privileges to conduct research studies by the HSD. For example, HSD human research projects typically involve:

- measurement of human health effects endpoints associated with controlled exposures to environmental pollutants such as ozone, carbon monoxide, volatile organic compounds, sulfur dioxide, particulate matter, nitrogen oxides, and noise, either alone or in combinations, which may include drugs or other substances;
- measurement of human health effects endpoints associated with environmental exposures in the atmosphere;
- *in vitro* exposures of cells or fluids to known or suspected toxicant agents;
- physiological and neurobehavioral assessment of populations potentially exposed to toxicant agents; and/or
- pharmacokinetics and dosimetry studies that characterize the fate and clearance of environmental agents.

The Contractor shall:

1. Recognize the Committee on the Protection of the Rights of Human Subjects (the Institutional Review Board (IRB) of the University of North Carolina at Chapel Hill School of Medicine) as the cognizant IRB for human studies conducted at the Human Studies Facility (HSF). If the Contractor has its own IRB, an inter-institutional agreement must be established between the Contractor's IRB and the Committee on the Protection of the Rights of Human Subjects within 2 months after Task Order award. Unless specifically exempted by the EPA Project Officer, the Committee on the Protection of the Rights of Human Subjects shall be the cognizant IRB.
2. Establish a Volunteer Recruitment Office in the HSF - The Contractor shall establish an office in space available on-site at the HSF to facilitate interaction with research volunteers and task order performance. The Contractor shall provide reception services to answer telephone and in-person inquiries from volunteers regarding experimental subject needs, and to greet volunteers reporting to the HSF to participate in research-related activities. HSD research activities are normally conducted between 7:30 A.M. and 5:00 P.M., Monday through Friday.
3. Recruit volunteers to participate in human experimental research projects - The Contractor shall solicit potential volunteers to participate in research studies. Volunteers include healthy young individuals as well as special populations potentially susceptible to pollutants (for example, children, elderly, mild asthmatics, people with respiratory disease, and smokers). Non English speaking populations may be desired. If non English speaking volunteers are required, the Contractor shall provide translation services for study-related materials. All recruiting activities must be pre-approved by the cognizant IRB.
4. Screen and make available volunteers to participate in approved protocols - The Contractor shall conduct screening tests as described below to identify human subjects qualified to participate in specific research studies. Qualification criteria will be specified in protocols approved by EPA management and the cognizant IRB.

The Contractor shall conduct initial screening tests on all volunteers based on general qualification criteria as well as requirements specified in each protocol. The initial screening process typically includes a telephone interview, and administering and preliminarily evaluating a medical history. Volunteers who satisfy the initial screening criteria shall be referred to the EPA for more sophisticated (advanced) screening procedures. These advanced screening tests will be performed by medical and/or research staff (not employees of the Contractor). Based on the advanced screening, the EPA will qualify individuals to participate in studies. The Contractor shall maintain an inventory of available volunteers and information about the studies for which they qualify. The Contractor shall provide volunteers an initial description of the studies they qualify to participate in and the payment schedules for those studies. Except for some medical history information, screening test data are typically considered valid for no more than one year requiring the tests be repeated for volunteers who remain active beyond that time.

5. Provide support for outside testing - When directed by the EPA Project Officer, the Contractor shall arrange, schedule, and arrange payment for study-related clinical testing not able to be performed at the HSF. These tests include, but are not limited to, analyses of blood samples, radiological exams, allergy testing, urine analyses, and ECG analyses. Test results will become part of each individual's confidential medical record.
6. Schedule volunteers for research activities - The Contractor shall schedule volunteers to be at the appropriate locations, at appropriate times, for research activities. Some studies and tests require scheduling standby volunteers to ensure that a study will run if the scheduled volunteer is unable to participate. The Contractor shall ensure that waiting intervals for subjects participation in multiple studies are maintained. To ensure staff and equipment availability, testing activities must be scheduled in advance. The Contractor shall also make necessary adjustments to scheduled activities, as well as potential appointment opportunities, to accommodate external influences such as staff and equipment availability.

The Contractor shall be responsible for communicating schedule information to both the volunteers and involved research staff. Communications with research staff shall be accomplished using computer tools developed or provided by the Contractor that facilitate remote access; the user interface (or client software) for these tools shall be made available to all staff involved in research supported by this effort and user training shall be provided as appropriate. The process must notify research staff of urgent changes affecting activities scheduled for the current or next business day (due to a volunteer cancellation for example). An updated schedule reflecting changes, including additions and deletions, shall be published, posted, or otherwise suitably made available no less frequently than daily. The Contractor shall obtain EPA Project Officer approval before implementing a system in response to the requirements of this paragraph.

7. Pay volunteers for study participation - The Contractor shall pay volunteers (including standby volunteers) as specified in each protocol for services rendered (including participation time and premium payments for participation in specific medical tests) and incidental expenses (such as food, parking, bus fare, taxi, and other travel costs) incurred by volunteers in the course of participating in HSD research. Volunteers shall be paid as services are rendered unless otherwise requested by the individual. The Contractor shall maintain records and file reports/forms required by state and Federal Agencies (for example, the Internal Revenue Service) related to payments made to volunteers.
8. Debrief volunteers following participation in screening and research activities - The Contractor shall, with cooperation of the volunteer, debrief volunteers who have participated in screening and research activities to obtain comments from them about their experience and to identify opportunities for improvement in paid volunteer relations. Summary information shall be reported to the EPA Project Officer through monthly progress reports or, if urgent, via memoranda.
9. Provide limited consulting for participating volunteers - Some studies may include administering and scoring the Minnesota Multiphasic Personality Inventory (MMPI-2™). The Contractor shall provide, upon volunteer request, limited consulting to explain MMPI-

2TM results to individuals required to complete the test. The services of a licensed Psychologist or comparably qualified practitioner shall be provided by the Contractor when a volunteer requests an interpretation of the MMPI-2TM test.

10. Provide information to research staff - The Contractor shall provide research staff information related to volunteer recruitment, screening, scheduling, and testing for EPA development or refinement of study protocols. When requested by the Project Officer, the contractor shall provide quantitative data, including but not limited to cost estimates, in relation to specific studies and/or taskings.
11. Maintain records - The Contractor shall maintain accurate and complete records of activities performed under the task order in both hard copy (paper) and electronic (soft copy) format. In addition to maintaining records to satisfy the reports of work requirements, volunteer-specific records are required. For each volunteer recruited, a hard copy history file containing the following elements is necessary:
 - a unique identifier for each volunteer (this is the EPA-provided medical record number for all volunteers referred to EPA during the screening process);
 - dates, times, and summary of all communications with volunteers, scheduled activities, and completed activities; and
 - screening and other Contractor-generated test data (the EPA medical staff will maintain records of clinical data resulting from advanced screening and outside testing).A database report containing the required history information is acceptable. A separate key (table) associating the unique volunteer identifiers and volunteer names shall also be maintained.

Records shall be maintained from the beginning of the recruiting process through records transfer to the EPA. Record keeping shall comply with Agency requirements found at <http://www.epa.gov/irmpoli8/polman/www.epa.gov/irmpoli8/polman/>. EPA will be responsible for archival and disposition of the records. All records shall be stored and processed in a manner to maintain volunteer confidentiality and privacy. At the end of the effort, the Contractor shall deliver all volunteer- and study-related records (including complete hard copy, electronic data files, and queries from computer databases or other information management tools) to the EPA Project Officer. The records shall be well organized and include an inventory (in electronic and hard copy formats) with brief descriptions of the general content of the delivered records/files.

12. Maintain training required for Contractor staff who interact with human subjects - The Contractor shall certify to the EPA Project Officer at the commencement of the task order and on each subsequent anniversary that Contractor staff interacting with human volunteer subjects have, at minimum, been trained in accordance with HSD requirements. These requirements include guidance established by the National Institutes of Health (NIH) for education of research teams participating in human research. An on-line course satisfying current NIH requirements is available via the Internet at <http://cme.nci.nih.gov>. Seminars that satisfy the requirements are also available locally (in the Chapel Hill, Raleigh, Durham area) at no or nominal cost. The Contractor shall be expected to adjust staff training as NIH guidance or HSD requirements are revised during the life of the task order.

13. Report progress and attend coordination meetings - The Contractor shall develop and deliver reports of work as specified in the Attachment "Reports of Work." In addition, representatives of the Contractor shall meet as needed with the EPA Project Officer and other staff to coordinate research activities, and discuss progress and issues.
14. Locate previous volunteers - Infrequently, it is necessary to contact volunteers to make them aware of new information about an HSD study in which they participated. Archived contact information (physical addresses, phone numbers, email addresses) may no longer be valid for some of the volunteers. The Contractor shall make reasonable efforts to find current contact information for these individuals.
15. Develop and maintain a World Wide Web site - The Contractor shall develop and maintain a hierarchy of pages on the World Wide Web dedicated solely to this task order. The Contractor shall provide or arrange for a suitable Web host for this purpose. At minimum, the web site shall:
 - provide information on current and planned studies to encourage new volunteer participation;
 - inform potential volunteers of current and upcoming studies;
 - disseminate information to volunteers and researchers regarding status of studies, schedules, and schedule changes;
 - comply with Federal and Agency requirements for disability access including Section 508 of the Rehabilitation Act of 1973, as amended (<http://www.access-board.gov/about/Rehab%20Act%20Amend-508.htm>), 29 U.S.C. 794d; and
 - provide hot links for prospective and recruited volunteers to communicate by e-mail with recruitment staff and investigators.

The site shall provide secure limited access to protect the privacy of individuals and maintain the confidentiality of data. All content and functionality displayed on these pages must be reviewed and approved by the cognizant IRB as well as the EPA Project Officer or his designee. The EPA Project Officer may propose specific content to be contained on these pages.

At the end of the performance period of the task order, the Contractor shall deliver on CD ROM to the EPA Project Officer, without restrictions, all electronic files, including but not limited to source files, associated with the web site in the hierarchical directory structure as they exist on the web server.

Performance Objective	Performance Standard	Acceptable Quality Level (AQL)	Monitoring Method	Incentive/Disincentive
Appropriate Volunteers	The Contractor shall provide appropriately screened volunteers that meet the criteria established in issued protocols.	No more than four (4) volunteers scheduled within a period of performance (base period or option year) that do not fully comply with protocol requirements.	The Project Officer will monitor and review Contractor reports and consider information provided by research investigators that could have impacted the contractor's ability to meet the performance objective.	A 10% deduction will be imposed on a subsequent invoice for each unqualified volunteer exceeding the AQL.
Volunteer Availability	The Contractor shall ensure Qualified volunteers are available to complete each study within the time frame established for each active protocol.	No studies unduly delayed by inadequate numbers of qualified volunteer subjects.	The Project Officer will monitor and review Contractor reports and consider information provided by research investigators, as well as the Contractor's effectiveness at identifying emerging problems and taking corrective action.	Document exemplary or less than satisfactory performance in past-performance report card.
Record Keeping/Reports of Work	The Contractor shall maintain adequate records and submit reports of work as stipulated in the SOW and Reports of Work.	No more than 2 incidents of inaccuracies or late deliveries shall occur within a period of performance (base period or option year).	The Project Officer will monitor and review Contractor reports.	Document exemplary or less than satisfactory performance in past-performance report card.
Web Development and Maintenance	The Contractor shall accurately develop and maintain a World Wide Web site in accordance with the SOW.	No more than four (4) incidents involving inaccuracies or inaccessibility within a period of performance (base period or option year).	Project Officer will randomly monitor and review the accuracy and accessibility of site.	Document exemplary or less than satisfactory performance in past-performance report card.

G. EVALUATION FACTORS:

The Government will make award to the responsible offeror(s) whose offer conforms to the requirements and is most advantageous to the Government, cost or other factors considered. For this requirement, all evaluation factors other than cost or price, when combined, are significantly more important than cost or price.

To expedite EPA evaluation and ensure evaluators identify pertinent information, technical proposals should be organized to follow and address each of the following evaluation criteria.

1. Technical Approach **25% Weight**

The offeror's proposal must demonstrate a full and complete understanding of the technical requirements by providing a detailed technical approach to the tasks and activities described in the Statement of Work. The offeror's understanding of this program should be further illustrated by including discussions of difficulties that are likely to occur during performance of this task order and how such difficulties would be overcome to satisfy the requirements of the task order. The offeror's approach must be technically sound, logistically appropriate, efficient, and comply with both 40 CFR Part 26 (*Protection of Human Subjects*) [available at http://www.access.gpo.gov/nara/cfr/waisidx_02/40cfr26_02.html] and EPA Order 1000.17 Change A1 (1999) (*Policy and Procedures on Protection of Human Subjects*) [available at http://www.epa.gov/oamrtpnc/forms/1000_17a.pdf].

2. Staffing Plan and Management Plan **25% Weight**

Offeror's shall describe their plans for staffing and managing this effort including the qualifications, abilities, and availability of the proposed staff and the offeror's managerial approach for establishing and maintaining systems to perform, monitor, and control work under the proposed task order. The staffing plan shall identify, by labor category, the occupational title of the individuals proposed and the number of work hours per year proposed for each occupational title. Proposals shall include the qualifications and demonstrated abilities of the individual(s) proposed to serve as key personnel. Proposals shall indicate whether key personnel are presently employed by the company and what proportion of their time would be made available for this task order, as well as the nature and extent of their commitment to other efforts. Offerors should describe specific sources of talent if personnel are not delineated in the proposal. Proposals shall describe the structure for managing the task order, detailing how work will be managed relative to the following topics.

- a. Management controls to ensure compliance with the requirements of all cognizant Institutional Review Boards and to protect volunteer-confidential information.
- b. The transition plan to be implemented following task order award including a time line for staffing the on-site recruitment office and establishing an infrastructure to support this effort.

The transition plan should specifically address the offeror's approach to quickly provide EPA pre-screened volunteers (for advanced screening) and identify the number of days required following award to begin satisfying this specific requirement.

- c. A comprehensive quality assurance (QA) program for the Statement of Work. The offeror shall describe their QA system, paying particular attention to the following areas:
- compliance with Federal, Agency, and IRB requirements for human research;
 - management of subcontracts including the qualification processes for vendors and subcontractors, especially with regard to clinically recognized certifications of outside testing laboratories and service providers;
 - records management and retention; and
 - other areas deemed important by the offeror.

3. Sample Plan to Recruit Special Populations 30% Weight

The proposal shall provide the offeror's approach to satisfy the following sample volunteer subject recruitment need. Although the sample provided is not an actual recruitment requirement, it is representative of the needs of some studies involving specialized populations. Considerations used in evaluating the offeror's approach will include its apparent feasibility, completeness, effectiveness, innovativeness, and compliance with policies to protect human subjects (identified elsewhere in the RFTOP).

Sample Recruiting Requirement -

A researcher is planning a study to evaluate the health effects of coarse particulate matter on asthmatic individuals. The protocol has been drafted except for the recruitment plan, which must be included prior to submission to EPA management and the Institutional Review Board (IRB) for approval. In accordance with the Statement of Work and Reports of Work, the EPA Project Officer has issued technical direction to the Contractor to prepare a Recruitment Survey. [For the purposes of this sample, the survey need only address the proposed recruitment strategies portion of the survey report; other elements of the report may be ignored.]

The following information is provided in the draft protocol:

The study will expose both healthy normal and otherwise healthy asthmatic individuals to concentrated ambient particulate matter (CAPs) at the EPA Human Studies Facility in Chapel Hill, NC. Data collection from participating volunteers is expected to be performed over a six month period from late spring to early fall. Each volunteer subject will be exposed once for two hours to clean air and once for two hours to CAPs; the exposures must be separated by at least two weeks and require a follow up visit to the Human Studies Facility on the days following exposures. In total, subjects will be required to spend approximately six hours at the Human Studies Facility on each of five days (one visit for informed consent and screening tests, two visits for exposures, and two visits for 24-hour post exposure testing). Subjects will be performing modest exercise during the two-hour exposures. Bronchoalveolar lavages will be performed by bronchoscopy 24 hours after each exposure.

In addition to receiving a thorough medical screening exam, subjects who complete all aspects of the study will receive compensation of approximately \$1,250.

The study requires 20 healthy normal and 20 otherwise healthy asthmatic individuals (40 subjects total). Subjects must be between the ages of 18 to 45 years. There are no gender or race based restrictions, however pregnant women are excluded. All subjects must be non-smokers for at least one year prior to study participation, have no history of cardiac disease, have a normal resting ECG, and have no recent or recurring exposure to pollutants or irritants.

4. Past Performance and Corporate Experience 20% Weight

The offeror must demonstrate their experience in managing efforts in research setting to accomplish the tasks and activities described in the Statement of Work as well as working with IRBs. Past Performance information provided by the offeror in their proposal shall include contracts/subcontracts/orders/grants of similar scope, size and complexity to this procurement during the last 3 years. The offeror must demonstrate record of quality services, completion of tasks within budget constraints, and established deadlines and achieving project goals and objectives. For each contract/subcontract/order/grant identified, include a brief synopsis identifying the client for whom the services were performed, the client point of contact, telephone and fax numbers.

H. SUPPLEMENTAL DATA:

KEY PERSONNEL

Program Manager - The program manager shall have at least:

- five years experience in recruiting volunteers for human studies (this may include clinical studies, drug trials, and comparable activities);
- a four year degree from an accredited college or university; and
- three years experience performing management activities involving staff supervision, customer service/relations, tracking costs and financial management, and report preparation.

Key personnel must remain available to the contract at the proposed level of effort for no less than the first 180 days.

GOVERNMENT FURNISHED PROPERTY

There is no government furnished property contemplated for this effort. The contractor shall be required to provide all equipment necessary to perform the effort.

SITE VISIT

Offerors or quoters are invited to inspect the site where services are to be performed and to satisfy themselves regarding all general and local conditions that may affect the cost of task order performance, to the extent that the information is reasonably obtainable. In no event shall failure to inspect the site constitute grounds for a claim after task order award. Contractors may visit the site where services are to be performed May 13, 2003 between 11:00am and 12:00 noon Eastern Standard Time. Please contact Mr. Ed Struble at (919) 966-6210 by May 12th at 12:00 Noon EST to make arrangements.

Contractors may submit questions to Ms. Frances Legg via email (legg.frances@epa.gov) no later than 12:00 noon EST May 16, 2003. Submitted questions and government responses to those questions will be posted by COB May 20, 2003 on the following website:
http://www.epa.gov/oam/rtp_cmd/

General Information

The following data is provided for informational purposes only and based on historical data. The types of studies, number of studies and number of subjects vary depending on program requirements.

- The HSD typically has between 10 and 25 human research studies active at any time.
- EPA historical data regarding numbers and types of studies and qualified volunteer subjects are summarized in tabular format below. The actual number of studies and qualified volunteers required will depend on study requirements. Qualified subjects are normally permitted to participate in more than one study in accordance with protocol-specified waiting periods.

	Base Year		Opt. Year 1		Opt. Year 2		Opt. Year 3		Opt. Year 4	
Study Type	No. of Studies	No. of Subj.	No. of Studies	No. of Subj.	No. of Studies	No. of Subj.	No. of Studies	No. of Subj.	No. of Studies	No. of Subj.
A	6	200	6	200	6	200	6	200	6	200
B	3	50	3	50	3	50	3	50	3	50
C	4	50	4	50	4	50	4	50	4	50
Total	13	300	13	300	13	300	13	300	13	300

- < Type A studies entail primarily healthy volunteers between 18 and 40 years of age. Monitoring and measurements are typically noninvasive and clinically routine.
 - < Type B studies entail primarily healthy volunteers between 18 and 40 years of age. Monitoring and measurements are generally more sophisticated than type A studies involving slightly greater risk; tests may include bronchoscopy, multiple blood draws, and administration of radio-labeled test materials.
 - < Type C studies typically require specialized populations such as mild asthmatics, the elderly (between 60 and 80 years of age), people with mild chronic obstructed pulmonary disease, and smokers. Monitoring and measurements are often more sophisticated than type A studies and may involve bronchoscopy and/or radio-labeled test materials.
- Reimbursable costs will not exceed the following amounts:
 - \$163,800 for the Base Period
 - \$171,900 for Option Period 1
 - \$180,400 for Option Period 2
 - \$189,300 for Option Period 3
 - \$198,600 for Option Period 4

I. TERMS AND CONDITIONS:

TERMS and CONDITIONS

SECTION B

B.1 Consideration and Payment (EP 52.216-160)

Consideration and payment will be made in accordance with the following:

ITEM DESCRIPTION	QTY	UNIT PRICE
TOTAL		
0001 <u>Base Period (10/22/03 - 10/21/04)</u>		
0001AA Supplies and services necessary to	12 MOS.	\$ _____
\$ _____		
establish and operate a Subject Recruitment Office as described in the Statement of Work. FIRM FIXED PRICE		

NOT TO

EXCEED

0001AB Cost Reimbursement Only - 1 YEAR
\$163,800 Subject Reimbursement for
Participation, Consulting Services,
Laboratory Services in accordance
with clause entitled
REIMBURSABLE COSTS
(Actual Cost Only)

TOTAL FOR BASE PERIOD \$

0002 Option Period 1 (10/22/04 - 10/21/05)

0002AA Supplies and services necessary to 12 MOS. \$ _____ \$
— establish and operate a Subject
Recruitment Office as described in
the Statement of Work.
FIRM FIXED PRICE

NOT TO EXCEED

0002AB Cost Reimbursement Only - 1 YEAR
\$171,900 Subject Reimbursement for
Participation, Consulting Services,
Laboratory Services in accordance
with clause entitled
REIMBURSABLE COSTS
(Actual Cost Only)

TOTAL FOR OPTION PERIOD 1 \$

0003 Option Period 2 (10/22/05 - 10/21/06)

0003AA Supplies and services necessary to 12 MOS. \$
\$
establish and operate a Subject
Recruitment Office as described in
the Statement of Work.

FIRM FIXED PRICE

NOT TO EXCEED

0003AB Cost Reimbursement Only - 1 YEAR

\$180,400 Subject Reimbursement for
Participation, Consulting Services,
Laboratory Services in accordance
with clause entitled
REIMBURSABLE COSTS
(Actual Cost Only)

TOTAL FOR OPTION PERIOD 2 \$

0004 Option Period 3 (10/22/06 - 10/21/07)

0004AA Supplies and services necessary to 12 MOS. \$
\$

establish and operate a Subject
Recruitment Office as described in
the Statement of Work.
FIRM FIXED PRICE

NOT TO EXCEED

0004AB Cost Reimbursement Only - 1 YEAR

\$189,300 Subject Reimbursement for
Participation, Consulting Services,
Laboratory Services in accordance
with clause entitled
REIMBURSABLE COSTS
(Actual Cost Only)

TOTAL FOR OPTION PERIOD 3 \$

0005 Option Period 4 (10/22/07 - 10/21/08)

0005AA Supplies and services necessary to 12 MOS. \$
\$

establish and operate a Subject
Recruitment Office as described in
the Statement of Work.
FIRM FIXED PRICE

NOT TO EXCEED

0005AB	Cost Reimbursement Only -	1 YEAR	\$
<u>198,600</u>	Subject Reimbursement for Participation, Consulting Services, Laboratory Services in accordance with clause entitled REIMBURSABLE COSTS (Actual Cost Only)		

TOTAL FOR OPTION PERIOD 4 \$

B.2 Limitation of Funds (EP 52.232.101)

a) Pursuant to the Limitation of Funds clause, incremental funding in the amount of TBD is allotted to cover estimated cost. The amount allotted for costs is estimated to cover the contractor's performance through TBD.

(b) When the contract is fully funded the Limitation of Cost clause shall become applicable.

SECTION C**C.1 Compliance with EPA Policies for Information Resources**

(a) Definition. Information Resources Management (IRM) is defined as any planning, budgeting, organizing, directing, training, promoting, controlling, and managing activities associated with the burden, collection, creation, use and dissemination of information. IRM includes both information itself, and the management of information and related resources such as personnel, equipment, funds, and technology. Examples of these services include but are not limited to the following:

(1) The acquisition, creation, or modification of a computer program or automated data base for delivery to EPA or use by EPA or contractors operating EPA programs.

(2) The analysis of requirements for, study of the feasibility of, evaluation of alternatives for, or design and development of a computer program or automated data base for use by EPA or contractors operating EPA programs.

(3) Services that provide EPA personnel access to or use of computer or word processing equipment, software, or related services.

(4) Services that provide EPA personnel access to or use of: Data communications; electronic messaging services or capabilities; electronic bulletin boards, or other forms of electronic information dissemination; electronic record-keeping; or any other automated information services.

(5) Services that are subject to the Brooks Act of 1965, as amended (Pub. L. 89-306).

(b) *General.* The Contractor shall perform any IRM related work under this task order in accordance with the IRM policies, standards and procedures set forth in this clause and noted below. Upon receipt of a work request (i.e. delivery order or work assignment), the Contractor shall check this listing of directives (see paragraph (d) for electronic access). The applicable directives for performance of the work request are those in effect on the date of issuance of the work request.

(1) IRM Policies, Standards and Procedures. The 2100 Series (2100-2199) of the Agency's Directive System contains the majority of the Agency's IRM policies, standards and procedures.

(2) Groundwater Program IRM Requirement. A contractor performing any work related to collecting Groundwater data; or developing or enhancing data bases containing Groundwater quality data shall comply with EPA Order 7500.1A - Minimum Set of Data Elements for Groundwater.

(3) EPA Computing and Telecommunications Services. The Enterprise Technology Services Division (ETSD) Operational Directives Manual contains procedural information about the operation of the Agency's computing and telecommunications services. Contractors performing work for the Agency's National Computer Center or those who are developing systems which will be operating on the Agency's national platforms must comply with procedures established in the Manual. (This document is only available through electronic access.)

(c) Printed Documents. Documents listed in (b) (1) and (b) (2) may be obtained from:

U.S. Environmental Protection Agency
Office of Administration
Facilities Management and Services Division
Distribution Section
Mail Code: 3204
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460
Phone: (202) 260-5797

(d) Electronic Access.

(1) Internet. A complete listing, including full text, of documents included in the 2100 Series of the Agency's Directive System, as well as the two other EPA documents noted in this clause, is maintained on the EPA Public Access Server on the Internet. Gopher Access: gopher.epa.gov is the address to access the EPA Gopher. Select 'menu keyword search' from the menu and search on the term 'IRM Policy'. Look for IRM Policy, Standards and Guidance. World Wide Web Access: <http://www.epa.gov> is the address for the EPA's www homepage. From the homepage, search on the term 'IRM Policy' and look for IRM Policy, Standards and Guidance.

(2) Dial-Up Modem. All documents, including the listing, are available for browsing and electronic download through a dial-up modem. Dial (919) 558-0335 for access to the menu that contains the listing for EPA policies. Set the communication parameters to 8 data bits, no parity, 1 stop bit (8,N,1) Full Duplex, and the emulator to VT-100. The information is the same whether accessed through dial-up or the Internet. For technical assistance, call 1-800-334-2405.

C.3 Key Personnel (EPAAR 1552.237-72)

(a) The Contractor shall assign to this contract the following key personnel:

1. Project Manager -

(b) During the first ninety (180) calendar days of performance, the Contractor shall make no substitutions of key personnel unless the substitution is necessitated by illness, death, or termination of employment. The Contractor shall notify the Contracting Officer within 15 calendar days after the

occurrence of any of these events and provide the information required by paragraph (c) below. After the initial ninety (180) calendar day period, the Contractor shall submit the information required by paragraph (c) to the Contracting Officer at least 15 calendar days prior to making any permanent substitutions.

(c) The Contractor shall provide an explanation of the circumstances necessitating the proposed substitutions, complete resumes for the proposed substitutes, and any additional information requested by the Contracting Officer. Proposed substitutes should have comparable qualifications to those of the persons being replaced. The Contracting Officer will notify the Contractor within 15 calendar days after receipt of all required information of the decision on substitutions. This clause will be modified to reflect any approved changes of key personnel.

SECTION G

G.1 Task Order Administrative Representatives (EP 52.242-100)

Project Officer(s) for this contract:

Project Officer:

MR. ED STRUBLE
Environmental Protection Agency
ORD/NHEERL (MD-58A)
Research Triangle Park, NC 27711

Phone: 919-966-6210
Fax: 919-966-6212

Alternate Project Officer:

DR. ELSTON SEAL
Environmental Protection Agency
ORD/NHEERL (MD-58A)
Research Triangle Park, NC 27711

Phone: 919-966-6217
Fax: 919-966-0655

Administrative Contracting Officer:

MS. ARDRA G. MORGAN

Environmental Protection Agency
RTP Procurement Operations Division (E105-02)
Research Triangle Park, NC 27711

Phone: 919-541-3670
Fax: 919-541-1075

G.2 Access to Government Property, Service and/or Space (RTP-G1)

1. The effort required to be accomplished under this task order must be performed at a Government facility. The Contractor shall be granted ingress and egress at such Government facility.
2. While Contractor personnel are at the Government facility, the Contractor is responsible for compliance with all laws, rules, and regulations governing conduct with respect to health and safety as they relate not only to their employees and agents, but also to other personnel who are Government employees or agents of the Government, and to property at the site regardless of ownership.
3. When the Contractor's team arrives at the Government facility, the team leader will make detailed arrangements with the Project Officer for access to and availability of the property, services, and space as listed hereafter.
4. While on Government premises and in possession of Government property, the Contractor is considered to be a bailee for hire, and subject to all duties thereof.
5. The Government property, services, and/or space as listed hereafter to which the Contractor shall have access under this clause shall be made available at the Government facility. In the event the property to which the Contractor is to have access is not made available as scheduled, the Contracting Officer shall, upon timely written request made by the Contractor, make a determination of the delay, if any, occasioned the Contractor thereby and shall equitably adjust the delivery or performance dates of the Contract and any other contractual provisions affected by any such delay, in accordance with the procedures provided for in the clause of the contract entitled "Changes."

LOCATION:

U.S. EPA Human Studies Facility
104 Mason Farm Road
Chapel Hill, NC 27514

1. Room 01, Subject Waiting Area, approximately 11' by 21'
2. Room 03, Reception Office, approximately 11' by 11'
3. Room 09, Copy Room, approximately 7' by 11'
4. Room 13, Office, approximately 10' by 14'
5. Room 15, Orientation/Testing Room, approximately 11' by 14'
6. Room 17, Office, approximately 10' by 14'

Telephone services, including long distance carrier and voice messaging, will be provided by the Government for contract-related activities. LAN server services (e.g., limited file storage and printer routing, access to EPA mail services, and limited Internet access) will also be provided, but the Contractor must provide the desk top computers, compatible LAN interface equipment, etc., and all office furnishings.

G.3 Submission of Invoices

The Contractor shall prepare a task order level invoice using Standard Form 1034, Public Voucher for Purchases and Services other than Personal to show the amount claimed for reimbursement. Submit to the address shown below, along with one copy to the Project Officer and one copy to the Contracting Officer. The Contractor may submit self-designed forms which contain the required information.

U.S. Environmental Protection Agency
RTP Financial Management Center (D143-02)
Attention: Contract Payment
Research Triangle Park, NC 27711

The invoice shall also provide a breakdown of current and cumulative charges for cost-reimbursable items including:

- payments to volunteers for participation in screening and study activities,
- outside testing,
- MMPI-2TM test materials,
- consulting services,
- special recruitment advertising,
- subcontracting costs for each subcontractor, and
- other (with an explanation of the charges).

Supporting documentation shall be provided for current cost amounts claimed. Cumulative charges must include the sum of charges by line item as well as the cumulative total for each task order period (e.g., Base Period, Option Period 1, Option Period 2, Option Period 3, and Option Period 4).

SECTION H

H.1 Option to Extend Task Order

The Government has the option to extend the term of this task order for 4 additional period(s). If the option period exceeds the current contract Options may be exercised subject to subsequent contract awards to the successful offeror in accordance with Clause B.2 of the NIH PICS MAS contract. If more than 60 days remain in the period of performance, the Government, without prior written notification, may exercise this option by issuing a task order modification. To exercise this option within the last 60 days of the period of performance, the Government must provide to the Contractor written notification prior to that last 60-day period. This preliminary notification does not commit the Government to exercising the option. Use of an option will result in the following task order modifications:

(a) The "Period of Performance" clause will be amended as follows to cover the Base and Option Periods:

Period	Start Date	End Date
Base Period	10/22/03	10/21/04
Option Period I	10/22/04	10/21/05
Option Period II	10/22/05	10/21/06
Option Period III	10/22/06	10/21/07
Option Period IV	10/22/07	10/21/08

The "Consideration and Payment" clause will be amended to reflect increased fixed prices for each option period.

H.2 Reimbursable Costs

Reimbursable costs are limited to reimbursement of actual costs only (no indirect costs or fee) for approved payments to volunteers for participation in human experimental studies, outside testing, MMPI-2TM test materials, consulting costs for a

licensed Psychologist or comparably qualified practitioner related to the MMPI-2TM tests, and special recruitment advertising.

Outside testing, for the purposes of this clause, is defined as study-related clinical testing and analyses not performed at the HSF. These tests include, but are not limited to, analyses of blood samples, radiological exams, allergy testing, urine analyses, and ECG analyses. Outside testing must be pre-approved by the EPA Project Officer.

Limited consulting services, for the purposes of this clause, are defined as the services of a licensed Psychologist or comparably qualified practitioner to score MMPI-2TM tests, and to provide an explanation of MMPI-2TM test scores to individuals who have participated in the screening tests and request a detailed interpretation of the results. Describing the test, the purpose for its use as a screening tool, and communication of test results are part of the Contractor's responsibilities and must be included in the fixed price.

Special recruitment advertising, for the purposes of this clause, is defined as advertising to recruit volunteers for studies requiring uniquely specialized populations (for example, individuals with specific degrees of chronic obstructive pulmonary disease [COPD] or specific types of heart disease). This unusual and exceptional advertising would be required to reach the desired population and may include, but is not limited to, media such as television. All special recruitment advertising costs must be pre-approved by the EPA Project Officer to be considered for cost reimbursement. All other advertising costs necessary for performance of the contract must be included in the fixed price.

H.3 Fixed Price Costs

Firm fixed price costs include all costs not specifically identified as reimbursable. Fixed price costs include costs associated with prime contractor labor; fringe benefits; all indirect costs including overhead, general and administrative costs (G&A); fees (profit); and all costs for routine advertising, testing supplies and materials, office supplies, shipping and mail, photocopy and publishing, computer equipment including software and software support, employee parking, and employee training.

The forms for administering the medical history (an approximately 30 page monochrome document) are to be included in the fixed costs. Contents and format of the medical history form will be defined by the EPA; the form is not protected by copyright.

H.4 Background Investigations for On-Site Contractor Personnel

All employees shall have a pre-employment investigation conducted prior to entering on duty for employment, and their personal qualifications must meet the Contractor's employment standards required for the position. This investigation shall include a search of local police files in the area of residence for the last five years and an inquiry of former employers and references. This investigation is to be conducted by the Contractor without additional cost to the Government, and be available for review by the representative of the Contracting Officer. A summary of the results of this pre-employment investigation shall be furnished to the PO within 30 days of the employee's entry on duty. An employee shall not be permitted to work without the employment investigation being completed.

H.5 Identification of On-Site Contractor Personnel (RTP-H.2)

All Contractor, subcontractor, and consultant personnel shall wear prominently displayed identification badges at all times when performing work on EPA property or attending meetings in the performance of this contract. The badge shall contain the individual's name, the company name and logo. When participating in such meetings (e.g., as a speaker, panel member), those individuals in Contractor employ must supplement physical identification (e.g., badges, placemarkers) with verbal announcements so that it is clear to the assembled group that they are employees of the Contractor, not Agency staff members. In addition, when working on EPA property, all contractor, subcontractor, and consultant personnel shall have signs visible on their desks or at their work sites that clearly state that they are not EPA employees.

H.6 Protection of Sensitive Information

It is anticipated that the contractor shall require access to sensitive information pertaining to subjects such as medical records, vital records, Government records, historic documents,

informed consent records, biological samples, personal identifiers (birth dates, addresses, social security numbers), and other sensitive records. The contractor shall protect such information and shall not disclose such data without prior written approval of the Project Officer.

H.7 Technical Direction

(a) The Project Officer is the primary representative of the Contracting Officer authorized to provide technical direction on task order performance.

(b) Individuals other than the Project Officer may be authorized to provide technical direction. If individuals other than the project officer are authorized to provide technical direction, their names will be specified in the task order as appropriate.

(c) Technical direction includes:

(1) Specific instruction to the contractor which assists the contractor in accomplishing the Statement of Work.

(2) Comments on and approval of reports or other deliverables.

(d) Technical direction must be within the task order statement of work. The Project Officer or any other technical representative of the Contracting Officer does not have the authority to issue technical direction which (1) institutes additional work outside the scope of the contract, delivery order, work assignment or technical direction document; (2) constitutes a change as defined in the "Changes" clause; (3) causes an increase or decrease in the estimated cost of the task order; (4) alters the period of performance; or (5) changes any of the other express terms or conditions of the task order.

(e) Technical direction will be issued in writing or confirmed in writing within five (5) calendar days after verbal issuance. One copy of the technical direction memorandum will be forwarded to the Contracting Officer and the Project Officer.

H.8 Organizational Conflict of Interest

(a) The Contractor warrants that, to the best of the Contractor's knowledge and belief, there are no relevant facts or circumstances which could give rise to an organizational

conflict of interest, as defined in FAR Subpart 9.5, or that the Contractor has disclosed all such relevant information.

(b) Prior to commencement of any work, the Contractor agrees to notify the Contracting Officer immediately that, to the best of its knowledge and belief, no actual or potential conflict of interest exists or to identify to the Contracting Officer any actual or potential conflict of interest the firm may have. In emergency situations, however, work may begin but notification shall be made within five (5) working days.

(c) The Contractor agrees that if an actual or potential organizational conflict of interest is identified during performance, the Contractor will immediately make a full disclosure in writing to the Contracting Officer. This disclosure shall include a description of actions which the Contractor has taken or proposes to take, after consultation with the Contracting Officer, to avoid, mitigate, or neutralize the actual or potential conflict of interest. The Contractor shall continue performance until notified by the Contracting Officer of any contrary action to be taken.

(d) Remedies - The EPA may terminate this task order for convenience, in whole or in part, if it deems such termination necessary to avoid an organizational conflict of interest.

(e) The Contractor agrees to insert in each subcontract or consultant agreement placed hereunder provisions which shall conform substantially to the language of this clause, including this paragraph, unless otherwise authorized by the Contracting Officer.

J. REPORTS/DELIVERABLES:

Unless specified elsewhere in the task order, all required deliverable documentation (except drafts) shall be delivered in both hard copy and electronic (soft copy) formats. One hard copy of each report shall be submitted to Administrative Contracting Officer and one hard copy to the EPA Project Officer. Electronic delivery may be by e-mail attachment to the Project Officer. Electronic copies of text, tabular, and data reports shall be delivered in a mutually agreeable software format.

Monthly Progress Report

The Contractor shall prepare and deliver monthly progress reports briefly discussing the progress made, any problems encountered, and remedial action taken to correct problems during the

reporting period. The report shall also discuss activities planned for the next reporting period. The report shall be submitted on or before the tenth (10th) business day following the end of the Contractor's monthly accounting period.

In addition to a general discussion of progress made, the monthly progress report shall include the following statistical information. Unless otherwise noted, the statistical data shall summarize activities for the current reporting period, cumulative amounts for the current performance period (year), and cumulative amounts for each completed performance period.

1. Summary of advertising activities and resulting volunteer contacts
2. Summary of recruiting activities including:
 - Number of individuals making initial contact to request information
 - Number of individuals requesting appointments for an initial office visit and/or screening
 - Number of individuals disqualified by telephone interviews
3. Summary of screening activities including:
 - Number of medical history interviews scheduled
 - Number of medical history interviews completed
 - Number of volunteers disqualified from current studies by medical history
 - Number of screening physical examinations scheduled
 - Number of screening physical examinations completed
 - Number of volunteers disqualified from current studies by advanced screening tests
4. Total number of volunteers qualified and available to participate in each active study at the end of the reporting period
5. Summary of research activities, by study, including:
 - Number of volunteer visits scheduled for each study
 - Number of volunteer visits canceled by:
 - < Principal investigators
 - < Medical staff
 - < The volunteer with explanation (*e.g.*, work, school, illness, protocol violation)
 - < The volunteer without explanation (*e.g.*, no shows)
 - Number of volunteer visits rescheduled following cancellation as a result of:
 - < Principal investigators
 - < Medical staff
 - < The volunteer with explanation
 - < The volunteer without explanation
 - Number of volunteer visits completed
 - Number of individual volunteers participating in each study by population type (for example, young healthy, elderly healthy, asthmatic, smoker, etc.) and in total
 - Number of individual volunteers withdrawing after starting a study but before completion (include the volunteer's reason for withdrawal if known) for the current reporting period

- Number of individual volunteers completing at least the minimum study requirements by population type (for example, young healthy, elderly healthy, asthmatic, smoker, etc.) and in total
6. Summary of financial data for the current reporting period, cumulative amounts for the performance period, and cumulative amounts for the total effort including:
- Reimbursable costs claimed under the task order by element of cost (such as payments to volunteers, outside testing, limited consulting services, etc.)
 - As directed by the EPA Project Officer, total study-specific recruiting, screening, testing, volunteer payment costs - The Agency requires tracking costs incurred for studies conducted in support of collaborative agreements and outside users for special accounting procedures. The EPA Project Officer will identify to the Contractor the studies requiring special study-specific cost tracking. The reported costs shall include a proration of fixed as well as applicable reimbursable costs allocable to each identified study.

Recruitment Survey

At the EPA Project Officer's request, the Contractor shall develop and deliver recruitment surveys for studies. Some studies involve very stringent criteria for selection of uniquely susceptible or responsive special populations limiting the number of volunteers available. The surveys shall address these issues with an assessment of volunteer availability, recruitment strategies, an estimate of the timetable for furnishing volunteers during the period of the proposed study, and recommendations for appropriate volunteer payment for participation. The reports must be submitted within ten (10) business days following each request.

TO # ICS-131 TITLE:Support Services for Human Studies Division of the EPA.

PART II - CONTRACTOR'S REPLY: CONTRACT #263-01-D-0_____

Contractor:

Points of Contact:

Phone-

Fax-

Address:

TOTAL ESTIMATED COST:

Pricing Method

TOTAL ESTIMATED NUMBER OF HOURS:

PROPOSED COMPLETION DATE:

FOR THE CONTRACTOR:_____

Signature

Date

SOURCE SELECTION:

WE HAVE REVIEWED ALL SUBMITTED PROPOSALS HAVE DETERMINED THIS FIRM SUBMITTED THE BEST OVERALL PROPOSAL AND THE PRICE/COST IS REASONABLE.

Billing Reference # _____

Appropriations Data: _____

RECOMMENDED:_____

FAX #

Signature - Project Officer

Date

APPROVED:_____

FAX #

Signature - Contracting Officer

Date

NIH APPROVAL -

CONTRACTOR SHALL NOT EXCEED THE ESTIMATED LABOR HOURS OR ESTIMATED TASK ORDER AMOUNT WITHOUT THE WRITTEN APPROVAL OF THE CONTRACTING OFFICER & PICS COORDINATOR

APPROVED:_____

Signature –Anthony M. Revenis, J.D., NIH-PICS Coordinator

Date